510(k) SUMMARY

10.1 Submitter's Name and Address

NOV 1 6 2001

CARDIAC SCIENCE, INC.
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Contact person:

Sew-Wah Tay, PhD
Vice President
Cardiac Science, Inc.
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10.2 Date Summary was Prepared

October 21, 2001

10.3 Device Name

Proprietary: Powerheart® Cardiac Rhythm Module™ (CRM™)

Common: Automatic External Cardioverter Defibrillator

10.4 Classification

1. 870.5300 DC-defibrillator
2. 870.5550 External Transcutaneous Cardiac Pacemaker (Noninvasive)
3. Class III 74 MJK

10.5 Predicate Device

Powerheart® AECD®, K993533

10.6 Description of Device

The Powerheart Cardiac Rhythm Module (CRM) is a compact, lightweight, automatic external cardioverter defibrillator. It incorporates essential circuitry and software to provide a detection/analysis/defibrillation/pacing system, in a single device, for monitoring and providing therapy to patients at risk for Sudden Cardiac Arrest.

10.7 Intended Use of Device

Indication for Use:

The Powerheart Cardiac Rhythm Module (CRM) is intended to acquire the ECG rhythm for the detection of, and to provide treatment for, ventricular tachyarrhythmias of patients who are at risk of sudden cardiac arrest. The device is intended to be used in medically supervised environments by trained personnel, in which patients are under the direct care of physicians and/or medical persons authorized by the state, province or country regulations in which they practice. The Powerheart CRM can be used in three modes: fully automatic mode, advisory mode or manual mode and includes a pacer which allows an operator to deliver external stimuli for temporary transcutaneous cardiac pacing. The Powerheart has previously undergone clinical testing on adults which support the safety and effectiveness of using the device on patients at risk of sudden cardiac arrest who are at least 8 years of age. The device is not classified as a wearable external defibrillator and is not intended for use in the home environment.

Fully Automatic Mode
In this mode, the device continuously monitors the patient's ECG rhythm, detects shockable ventricular tachyarrhythmias and automatically provides defibrillation therapy for the treatment of sudden cardiac arrest.

Advisory (AED) Mode
In this mode, the device continuously monitors the patient's ECG rhythm, detects shockable ventricular tachyarrhythmias and advises the operator to press the shock button to deliver defibrillation therapy for the treatment of sudden cardiac arrest.

Manual Mode
In this mode, as is the case with all standard manual defibrillators, the operator manually selects the energy setting, manually selects the charge button, determines if the patient has a shockable ventricular tachyarrhythmia and decides when to manually deliver defibrillation therapy.

Pacing
The device includes a non-invasive external pacer that allows a physician and/or trained medical person to provide temporary external cardiac pacing for patients with symptomatic bradycardia or asystole.

10.8 Summary of Technological Characteristics

The Powerheart CRM utilizes an FDA-cleared and patented arrhythmia detection software that continuously monitors, detects and delivers therapy, according to physician-prescribed parameters, to patients experiencing ventricular tachyarrhythmias. The delivery output is an FDA-cleared, biphasic truncated exponential waveform, which the Powerheart CRM can transmit in one of three modes: Automatic, Advisory and Manual. The Powerheart CRM also provides non-invasive temporary cardiac pacing.

10.9 Summary of Performance Data

The performance tests conducted on the Powerheart Cardiac Rhythm Module will follow the applicable portions of the ANSI/AAMI DF2 and DF39 requirements for cardiac defibrillator devices and automatic external defibrillators to demonstrate the safety and efficacy of the CRM device.

10.10 Conclusion

The performance tests conducted on the Powerheart CRM will be subjected to pre-determined pass criteria that will support claims of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 6 2001

Sew-Wah Tay, Ph.D.
Vice President
Cardiac Science, Inc.
5420 Feltl Road
Minneapolis, MN 55343

Re: K012197
Trade Name: Powerheart® Cardiac Rhythm Module
Regulation Number: 21 CFR 870.5300
Regulation Name: Defibrillator, Automatic, External
Regulatory Class: Class III (three)
Product Code: MKJ, LDD, DRO
Dated: October 29, 2001
Received: October 30, 2001

Dear Ms. Tay:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K012197

NOV 1 6 2001

Device Name: Powerheart® Cardiac Rhythm Module

Indication for Use:

The Powerheart Cardiac Rhythm Module (CRM) is intended to acquire the ECG rhythm for the detection of, and to provide treatment for, ventricular tachyarrhythmias of patients who are at risk of sudden cardiac arrest. The device is intended to be used in medically supervised environments by trained personnel, in which patients are under the direct care of physicians and/or medical persons authorized by the state, province or country regulations in which they practice. The Powerheart CRM can be used in three modes: fully automatic mode, advisory mode or manual mode and includes a pacer which allows an operator to deliver external stimuli for temporary transcutaneous cardiac pacing. The Powerheart has previously undergone clinical testing on adults which support the safety and effectiveness of using the device on patients at risk of sudden cardiac arrest who are at least 8 years of age. The device is not classified as a wearable external defibrillator and is not intended for use in the home environment.

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(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
K012197

Prescription Use ✓ OR Over-The Counter Use_____
(Per 21 CFR 801.109)